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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,640	02/20/2004	Raymond P. Silkaitis	7135USO3	7339

41155 7590 03/17/2009

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EXAMINER	
SOREY, ROBERT A	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,640	SILKAITIS ET AL.	
	Examiner	Art Unit	
	ROBERT SOREY	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. In the amendment filed 01/08/2009, the following occurred: claims 1-3, 5, and 6 were amended; and claim 7 was added. Claims 1-7 are presented for examination.

Response to Amendments

2. Applicant's amendments to claims 1-3, 5, and 6, and the addition of claim 7, appear to not add new matter and will be treated below on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claim 6** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. As per claim 6, Applicant teaches "programming code executed by the processor to receive the delivery program code and the digital photo of the patient and to place the digital photo of the patient and the delivery program code on the display of the medical pump", but it is unclear as to what exactly is meant by *placing the delivery program code on the medical pump display.* As it appears to be claimed, is the actual program coding (e.g., C+, Java, FORTRAN, etc.) being shown or the display?

6. As per claim 7, Applicant teaches "wherein the medical pump is associated with the patient by the medical management system via the steps of reading a machine readable label on the medical pump and reading a machine readable label on one of the

patient and a medication container", but it is unclear as to what reads these labels, how the labels are read, and how that device is incorporated into Applicant's method.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. **Claims 1-6** are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 7,154,397 to Zerhusen et al.

9. As per claim 1, Zerhusen et al. teaches a method for a caregiver to validate the right patient with visual confirmation between the patient and a display of a medical pump in a medical management system (Fig. 3B, ele. 80)(see: Zerhusen et al., column 15, lines 1-3, is met by "[a]n image or photo... of the patient is also illustratively displayed to confirm that the patient is the correct patient"), comprising:

--*storing a digital photo of a patient* (see: Zerhusen et al., column 1, lines 55-65, is met by "[p]atient data is stored in a memory of the point-of-care computer or in a main server");

--*transmitting the digital photo to the medical pump* (Fig. 1, ele. 32 and 34; Fig. 2, ele. 34; and Fig. 129)(see: Zerhusen et al., column 1, lines 26-65, is met by "[a]ccess to all patient information is available to…any computer connected to the point-of-care

computer through a communication network" where the point of care includes the display and the therapeutic medical device including an IV pump; column 6, lines 1-7 and lines 36-41, is met by "signals can be transmitted between the network…and computer"; and column 27, lines 17-57); *and*

--placing the digital photo of the patient on the display of the medical pump (see: Zerhusen et al., column 1, lines 26-65; and column 6, lines 1-7, is met by "[a]n image or photo…of the patient is also illustratively displayed").

10. As per claim 2, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--transmitting the digital photo to the medical pump when delivery programming code associated with a medication order for the patient is transmitted to the medical pump (Fig. 126, especially ele. 1524; and Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 1, lines 26-65, is met by "[a]ccess to all patient information is available to…any computer connected to the point-of-care computer through a communication network" where the point of care includes the display and the therapeutic medical device including an IV pump; column 5, lines 54-57, is met by the computer being used "to provide controlled medication administration"; column 6, lines 1-7 and lines 36-41, is met by "signals can be transmitted between the network…and computer"; column 25 line 37 through column 26, line 39, is met by the message to the nurse indicating a medication delivery on his or her do-to list and the step of identifying the correct patient; column 27, lines 17-57; and column 40, lines 5-9, is met by treatment device coupled to the computer to control and monitor operation of the treatment device).

11. As per claim 3, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--transmitting the digital photo to the medical pump when the device has been associated with the patient by the medical management system (Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 2, lines 6-14, is met by identification signals being sent to and used by the medical management system devices to associate people and things with the system; and column 26, lines 23-39, is met by displaying "an image of the patient along with a display of the patient's name for viewing by the nurse").

12. As per claim 4, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--prompting the caregiver with the display to confirm that the patient matches the digital photo on the display (Fig. 128, ele. 1548, 1550, and 1552)(see: Zerhusen et al., column 14, line 56 through column 15, line 3; and column 26, lines 23-39, is met by "the nurse can verify that the patient being attended to is in fact the patient maintained in the hospital main database").

13. As per claim 5, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 4, and further teaches:

--sending a confirmation that the patient matches the digital photo to a medication management unit (Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 14, line 56 through column 15, line 3; and column 26, lines 23-39, is met by "[i]f the correct patient is identified…then the nurse identification information is entered") *as a right patient match in a five rights check.*

14. As per claim 6, Zerhusen et al. teaches a medication management system for a caregiver to validate the right patient with visual confirmation between the patient and a display of a medical pump in a medical management system (Fig. 3B, ele. 80)(see: Zerhusen et al., column 15, lines 1-3, is met by "[a]n image or photo... of the patient is also illustratively displayed to confirm that the patient is the correct patient"), comprising:

--a medication management unit having a processing unit and a storage medium coupled to the processing unit (Fig. 1 and Fig. 2)(see: Zerhusen et al., column 5, lines 26-35), *the storage medium containing programming code executed by the processing unit to* (see: Zerhusen et al., at least column 5, lines 57-62, is met by "software" throughout):

--store a digital photo of a patient (see: Zerhusen et al., column 1, lines 55-65, is met by "[p]atient data is stored in a memory of the point-of-care computer or in a main server"), *transmit delivery program code to the medical pump* (Fig. 1, ele. 32 and 34; Fig. 2, ele. 34; and Fig. 129)(see: Zerhusen et al., column 1, lines 26-65, is met by "[a]ccess to all patient information is available to…any computer connected to the point-of-care computer through a communication network" where the point of care includes the display and the therapeutic medical device including an IV pump; column 5, lines 54-57, is met by the computer being used "to provide controlled medication administration"; column 6, lines 1-7 and lines 36-41, is met by "signals can be transmitted between the network…and computer"; column 27, lines 17-57; and column 40, lines 5-9, is met by treatment device coupled to the computer to control and monitor operation of the treatment device), *and transmit the digital photo to the medical pump*

(Fig. 1, ele. 34; Fig. 2, ele. 34; and Fig. 129)(see: Zerhusen et al., column 1, lines 55-65, is met by "[a]ccess to all patient information is available to…any computer connected to the point-of-care computer through a communication network"; column 6, lines 36-41, is met by "signals can be transmitted between the network…and computer"; and column 27, lines 17-57); *and*

--a medical pump in electronic communication with the medication management unit, having a processor and a memory coupled to the processor, the memory containing programming code executed by the processor to receive the delivery program code and the digital photo of the patient and to place the digital photo of the patient and the delivery program code on the display of the medical pump (Fig. 42, ele. 624)(see: Zerhusen et al., column 1, lines 55-65, is met by "[a]n image or photo…of the patient is also illustratively displayed").

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. **Claims 1-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,154,397 to Zerhusen et al. in view of U.S. Patent Application Publication 2002/0038392 to De La Huerga.

17. As per claim 1, Zerhusen et al. teaches a method for a caregiver to validate the right patient with visual confirmation between the patient and a display in a medical

management system (Fig. 3B, ele. 80)(see: Zerhusen et al., column 15, lines 1-3, is met by "[a]n image or photo... of the patient is also illustratively displayed to confirm that the patient is the correct patient"), comprising:

--*storing a digital photo of a patient* (see: Zerhusen et al., column 1, lines 55-65, is met by "[p]atient data is stored in a memory of the point-of-care computer or in a main server");

--*transmitting the digital photo* (Fig. 1, ele. 34; Fig. 2, ele. 34; and Fig. 129)(see: Zerhusen et al., column 1, lines 55-65, is met by "[a]ccess to all patient information is available to…any computer connected to the point-of-care computer through a communication network"; column 6, lines 36-41, is met by "signals can be transmitted between the network…and computer"; and column 27, lines 17-57); *and*

--*placing the digital photo of the patient on the display* (see: Zerhusen et al., column 1, lines 55-65, is met by "[a]n image or photo…of the patient is also illustratively displayed").

Zerhusen et al. teaches a display that "receive[s] information automatically from various monitors and medical devices such as vital signs monitor, bed therapy systems, IV pumps, and the like" (see: Zerhusen et al., column 1, lines 26-43) and that "[p]atient monitors 28, treatment devices 30, and therapy devices 32 are also coupled to computer 12", computer 12 itself connected to display 24 taught by Zerhusen et al. (Fig. 1)(see: Zerhusen et al., column 6, lines 1-7), but fails to specifically point out that the display is part of or directly affixed to a *medical pump*; however, De La Huerga teaches a medication pump with a display (Fig. 17, ele. 100 and 123)(see: De La Huerga,

paragraphs 145, 148-151, and 164). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Zerhusen et al. and De La Huerga. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

18. As per claim 2, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--transmitting the digital photo to the medical pump when delivery programming code associated with (Fig. 17)(see: De La Huerga, paragraph 145-152, is met by the pump receiving information, including delivery parameters) *a medication order for the patient is transmitted to the medical pump* (Fig. 126, especially ele. 1524; and Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 25 line 37 through column 26, line 39, is met by the message to the nurse indicating a medication delivery on his or her do-to list and the step of identifying the correct patient).

19. As per claim 3, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--transmitting the digital photo to the medical pump when the device has been associated with the patient by the medical management system (Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 2, lines 6-14, is met by identification signals being sent to and used by the medical management system devices to associate people and

things with the system; and column 26, lines 23-39, is met by displaying “an image of the patient along with a display of the patient’s name for viewing by the nurse”).

20. As per claim 4, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--prompting the caregiver with the display to confirm that the patient matches the digital photo on the display (Fig. 128, ele. 1548, 1550, and 1552)(see: Zerhusen et al., column 14, line 56 through column 15, line 3; and column 26, lines 23-39, is met by “the nurse can verify that the patient being attended to is in fact the patient maintained in the hospital main database”).

21. As per claim 5, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 4, and further teaches:

--sending a confirmation that the patient matches the digital photo to a medication management unit (Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 14, line 56 through column 15, line 3; and column 26, lines 23-39, is met by “[i]f the correct patient is identified…then the nurse identification information is entered”) *as a right patient match in a five rights check.*

22. As per claim 6, Zerhusen et al. teaches a medication management system for a caregiver to validate the right patient with visual confirmation between the patient and a display in a medical management system (Fig. 3B, ele. 80)(see: Zerhusen et al., column 15, lines 1-3, is met by “[a]n image or photo... of the patient is also illustratively displayed to confirm that the patient is the correct patient"), comprising:

--a medication management unit having a processing unit and a storage medium coupled to the processing unit (Fig. 1 and Fig. 2)(see: Zerhusen et al., column 5, lines 26-35), *the storage medium containing programming code executed by the processing unit to* (see: Zerhusen et al., at least column 5, lines 57-62, is met by "software" throughout):

--store a digital photo of a patient (see: Zerhusen et al., column 1, lines 55-65, is met by "[p]atient data is stored in a memory of the point-of-care computer or in a main server"), *and transmit the digital photo* (Fig. 1, ele. 34; Fig. 2, ele. 34; and Fig. 129)(see: Zerhusen et al., column 1, lines 55-65, is met by "[a]ccess to all patient information is available to…any computer connected to the point-of-care computer through a communication network"; column 6, lines 36-41, is met by "signals can be transmitted between the network…and computer"; and column 27, lines 17-57); *and*

--electronic communication with the medication management unit, having a processor and a memory coupled to the processor, the memory containing programming code executed by the processor to receive the delivery program code and the digital photo of the patient and to place the digital photo of the patient and the delivery program code on the display (Fig. 42, ele. 624)(see: Zerhusen et al., column 1, lines 55-65, is met by "[a]n image or photo…of the patient is also illustratively displayed").

Zerhusen et al. teaches a display that "receive[s] information automatically from various monitors and medical devices such as vital signs monitor, bed therapy systems, IV pumps, and the like" (see: Zerhusen et al., column 1, lines 26-43) and that "[p]atient

monitors 28, treatment devices 30, and therapy devices 32 are also coupled to computer 12", computer 12 itself connected to display 24 taught by Zerhusen et al. (Fig. 1)(see: Zerhusen et al., column 6, lines 1-7), but fails to specifically point out that the display is part of or directly affixed to a *medical pump* and *transmit delivery program code to the medical pump*; however, De La Huerga teaches a medication pump with a display (Fig. 17, ele. 100 and 123)(see: De La Huerga, paragraphs 145, 148-151, and 164) wherein the pump receives information, including delivery parameters (Fig. 17)(see: De La Huerga, paragraph 145-152). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Zerhusen et al. and De La Huerga. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

23. As per claim 7, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 6, and further teaches:

--*wherein the medical pump is associated with the patient by the medical management system via the steps of reading a machine readable label on the medical pump and reading a machine readable label on one of the patient and a medication container* (see: Zerhusan et al., paragraph 30 and 41, is met by a controller to check machine readable patient wristband, IV bag information, and IV pump identification; and paragraph 30, 39, 103, 151, 157, 247, 249, and 275, is met by medicant bag check against pump and associated patient identification using machine readable labels).

Response to Arguments

24. Applicant's arguments from the response filed on 01/08/2009 have been fully considered and will be addressed below in the order in which they appeared.

25. In the remarks, Applicant argues in substance that (1) "Zechusen et al, focus on oral medications (see FIGS. 53 and 128 - "MEDs HELD DOWN?" or "Patient Accepts Med") and fail to disclose or fairly suggest that the patient photo is displayed on a display screen of a medical pump, such as an electronic programmable medical pump that is adapted to deliver medications intravenously or by other non-oral routes. In fact, Zerhusen et al. teach away from locating the display screen on a medical pump. See the separate treatment and therapy devices 30, 32 and locked medication box 46 in FIG. 1. For flexibility, the approach of Zerhusen et al, is clearly bed-centric and device non-specific with respect to its preferred display locations".

26. As per Applicant's argument that (1) "Zechusen et al, focus on oral medications (see FIGS. 53 and 128 - "MEDs HELD DOWN?" or "Patient Accepts Med") and fail to disclose or fairly suggest that the patient photo is displayed on a display screen of a medical pump, such as an electronic programmable medical pump that is adapted to deliver medications intravenously or by other non-oral routes. In fact, Zerhusen et al. teach away from locating the display screen on a medical pump. See the separate treatment and therapy devices 30, 32 and locked medication box 46 in FIG. 1. For flexibility, the approach of Zerhusen et al, is clearly bed-centric and device non-specific with respect to its preferred display locations", the Examiner respectfully disagrees.

Applicant's arguments are not persuasive. The claims are rejected twice.

In the first instance, it is determined that Zechusen et al. does teach a computer and display attached to an IV pump as claimed. Applicant argues that "Zerhusen et al. teach away from locating the display screen on a medical pump" because in Fig. 1 the treatment and therapy devices are shown as being connected to the computer and display but each are shown in different boxes. However, because the therapy and treatment devices are connected to the computer and display and are in communication with each other, they are considered part of the same device. Through numerous figures in Zerhusen et al. teach that the computer and display connected to the therapy and treatment devices are located at the same point of care and even on the same IV pump stand in many cases. Furthermore, any nonfunctional difference relates to design choice and intended use, and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim, as is the case here. Additionally, Applicant does not teach the location of the display screen of the medical pump. Applicant claims "a display of a medical pump", but the proximity of the display to the medical pump is not specified. In response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., the proximity of the display to the medical pump) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In the second instance, the Examiner argues in the alternative and considers the case where Zerhusen et al. does not teach the invention as claimed. Here, though Applicant's arguments with respect to arguments (1) have been considered, they are moot in view of the new ground(s) of rejection—specifically, in view of the De La Huerga reference. De La Huerga teaches displays on IV pumps and is combined with proper rationale to incorporate elements of the display of the Zerhusen et al. reference. De La Huerga further teaches the use of machine readable labels to associate elements of the medical management system.

Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT SOREY whose telephone number is (571)270-3606. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM (EST).

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on (571)272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3626
March 13, 2009

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626